

Appl. No. 10/570835
Amdt. dated July 16, 2007
Reply to Office Action of April 9, 2007

Remarks/Arguments

1. Applicant thanks Examiner for the careful review of the present application, as evidenced by the Office Action of April 9, 2007. In that Office Action, Examiner rejected all pending claims 5-10.
2. **Amendments to the Claims:** Claim 5 was amended to recite a protective sack for receiving the organ in the perfusion chamber and providing a barrier between the organ and the dialysate. Language supporting this element is found in paragraph [0012] of the Substitute Specification and shown in FIG. 1. Language was added to claim 5 to clarify that the vitality-preserving fluid circuit includes a dialysate circulation system and a perfusate circulation system and also that the dialysate stored in the organ perfusion chamber is a component of the dialysate circulation system and is integrated into that system as needed. Language supporting this amendment is found in paragraph [0008] of the Substitute Specification. The limitation that the organ is maintained in a floating state by the dialysate storage fluid was also added to claim 5. Language supporting this amendment is found in paragraphs [0007] and [0013] of the Substitute Specification. Claim 8 was amended to recite a wall of the organ perfusion chamber and claim 9 amended to reference said wall. A wall is shown in FIG. 1. New dependent claim 11 was added to further claim a protective sack that is an impermeable plastic bag. Language supporting this claim is found in paragraph [0012]. These amendments introduce no new subject matter and Applicant requests approval and entry of the amended claims.
3. **Nonstatutory Double Patenting Rejection:** Examiner provisionally rejected claims 5 – 9 as being unpatentable over claims 21, 28 – 32, and 35 – 37 of co-pending application no. 10/570920 in view of Brasile (U.S. Patent Application Publication

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2002/0012988). The co-pending application is directed toward the perfusion circulation system, whereas the current application is directed toward an organ perfusion chamber that contains a protective sack for receiving a transplant organ and that also serves as a reservoir for dialysate fluid. Thus, the two co-pending applications are directed toward separate and distinct inventions. Applicant will submit a terminal disclaimer as necessary when the claims of the co-pending application are examined. With regard to the currently amended claims of the present application, Applicant submits that Brasile is no longer applicable as prior art and requests that the rejection based on Brasile be withdrawn.

4. Rejections under 35 U.S.C. § 112: Examiner rejected claims 5-10 as being indefinite for failing to particularly point out and distinctly claim the subject matter being claimed. Claim 5 has been amended to clarify that the vitality-preserving fluid comprises a dialysate circulation system and a perfusate circulation system and that the dialysate is a component of the dialysate circulation system. Claim 8 has been amended to recite an organ perfusion chamber "having a wall". Claim 9 has been amended to recite "into said" wall. These amendments have eliminated the indefinite language and Applicant requests that Examiner withdraw this rejection.

5. Rejection under 35 U.S.C. § 102(b): Examiner rejected claims 5 and 6 as being anticipated by U.S. Patent Application 2002/0012988 (Brasile). Brasile discloses an organ chamber for holding an organ. Transplant organs are frequently transported, by helicopter, airplane, or road vehicle, to distant locations. The storage chamber is understandably jostled during such transport. An organ stored loosely in a chamber would bump up against the walls during such transport, and this could cause serious damage to the organ tissue. As a result, efforts are made to handle transplant organs

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very carefully and to prevent them from being bumped or jostled. The **Brasile** organ chamber comprises a container and a support member for supporting the organ and inhibiting movement of the organ. The **Brasile** support member has a shape or consistency that allows it to cradle the organ, to keep the organ from bumping up against the walls of the storage container. **Brasile** discloses various types of support members, such as, gel-filled pads or slings, which are capable of adapting to some extent to the shape of the particular organ. Thus, the **Brasile** sling or gel-filled pad cradles the organ on the bottom and partially on the sides, but does not enclose the organ. **Brasile**, paragraphs [0065], [0066], [0067]. Furthermore, the organ storage chamber is otherwise not filled with a fluid that supports the weight of the organ to hold it in a floating state.

6. By contrast, the organ perfusion chamber of the present application, as claimed in claim 5, simultaneously serves as a storage chamber for the transplant organ and as a reservoir for dialysate. The organ is encased in the protective covering or sack, which serves as a barrier between the organ and the dialysate storage fluid. The dialysate storage fluid supports the organ in a floating state, which prevents the organ from bumping into the walls of the chamber under normal transport conditions.

7. A further feature of the organ perfusion chamber of the present application that is not disclosed in the prior art is the dual use of the chamber as a reservoir for the dialysate. Storage of the relatively large mass of dialysate fluid helps maintain the organ at an even temperature, because the mass of the dialysate fluid contributes to a even storage and distribution of heat within the chamber. The reservoir also keeps the dialysate, a component of the vitality-preserving circuit, at temperature and readily available to be added to the dialysate or vitality-preserving circuit as needed.

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8. The **Brasile** reference does not disclose an organ perfusion chamber that has all the elements of the chamber claimed in the present application. It does not disclose a chamber that serves simultaneously as a storage chamber for an extracorporeal organ and for dialysate fluid, or for any fluid that is a component of the vitality-preserving fluid circuit. It does not disclose a protective covering that protects the organ in the chamber from the dialysate. Applicant submits that **Brasile** does not anticipate the invention of the present application, and that the invention claimed in currently amended claim 5 contains allowable subject matter that is clearly distinguishable from the cited prior art. Applicant further notes that claim 6 depends directly from claim 5 and therefore contains the allowable subject matter of claim 5. Applicant therefore requests that Examiner withdraw the rejections based on **Brasile**.

9. **Rejections under 35 U.S.C. § 103(a):** Examiner rejected claims 5, 6, 8 and 9, as being unpatentable over **Brasile**. Claim 5, as amended, recites an organ perfusion chamber with a protective sack that supports an organ in a floating state inside a chamber filled with dialysate storage fluid. **Brasile** does not render this invention obvious as it does not teach, suggest, or motivate one skilled in the art to use a protective sack to protect an organ maintained in an organ perfusion chamber from a dialysate stored in the chamber, the organ being maintained in a floating state by the storage fluid. Claims 6, 8 and 9 depend indirectly from claim 5, which contains allowable subject matter. Accordingly, claims 6, 8 and 9 contain the allowable subject matter of claim 5. Applicant respectfully requests that Examiner withdraw this rejection of claims 5, 6, 8, and 9.

10. Examiner rejected further claims 5, 6, 8 – 10 as being unpatentable over **Brasile**, and further in view of U.S. Patent 5,285,657 (Bacchi et al; 1994). **Bacchi** discloses an

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insulated organ perfusion chamber with an hermetically sealed lid for organ transport. Claims 6, and 8 – 10 depend directly or indirectly from claim 5, which as amended, contains allowable subject matter. Accordingly, claims 6 and 8 – 10 contain the allowable subject matter of claim 5. Applicant respectfully requests that Examiner withdraw this rejection and allow these claims.

11. Applicant has successfully traversed all rejections and submits that all claims currently pending include allowable subject matter. Applicant therefore requests that Examiner withdraw all rejections and allow currently presented claims 5 – 11.

12. Examiner is respectfully invited to call or email the Undersigned, should there be any issues that can be quickly clarified with this type of communication.

13. This paper is being filed within three months of the issue date of the Office Action. No additional late fees or other fees are due. Should, however, other fees be deemed necessary, the Undersigned herewith authorizes permission to deduct such fees as necessary from the Deposit Account No. 501 517.

Respectfully submitted,



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